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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,855	03/01/2002	Robert F. Bargatze	048984-5002	5470

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,855	BARGATZE ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 39-45, 47, 51-59 and 64-66, drawn to antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 38kDa and pharmaceutical compositions comprising said antibodies.

Group II, claim(s) 39-45, 47-48, 51-59 and 64-66, drawn to antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 37kDa and pharmaceutical compositions comprising said antibodies.

Group III, claim(s) 39-47, 51-59 and 64-66, drawn to antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 40kDa and pharmaceutical compositions comprising said antibodies.

Group IV, claim(s) 38-45, 47, 49-60 and 64-66, drawn to antibodies (including 1C1) that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 41kDa and pharmaceutical compositions comprising said antibodies.

Group V, claim(s) 39-46, 48, 51-59 and 64-66, drawn to antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 54kDa and pharmaceutical compositions comprising said antibodies.

Group VI, claim(s) 39-48, 51-59 and 64-66, drawn to antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 59kDa and pharmaceutical compositions comprising said antibodies.

Group VII, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 38kDa.

Group VIII, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 37kDa.

Group IX, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 40kDa.

Group X, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 41kDa.

Group XI, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 54kDa.

Group XII, claim(s) 61-63, drawn to a method of treating candidiasis utilizing antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 59kDa.

Group XIII, claim(s) 71, 73-77, drawn to a method of treating candidiasis utilizing 5F8 monoclonal antibodies.

Group XIV, claim(s) 71, 73-77, drawn to a method of treating candidiasis utilizing 5D8 monoclonal antibodies.

Group XV, claim(s) 71-77, drawn to a method of treating candidiasis utilizing 1C1 monoclonal antibodies.

Group XVI, claim(s) 71, 73-77, drawn to a method of treating candidiasis utilizing 6C5 monoclonal antibodies.

Group XVII, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 36kDa.

Group XVIII, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 38kDa.

Group XIX, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 40kDa.

Group XX, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 41kDa.

Group XXI, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 54kDa.

Group XXII, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 55kDa.

Group XXIII, claim(s) 67-69, drawn to hydrophobic cell wall protein of a yeast of the *Candida* genus wherein the molecular weight is about 59kDa.

Group XXIV, claim(s) 78-80, drawn to methods of determining whether an antibody binds to an epitope of a hydrophobic cell wall protein.

The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited **product**, antibodies that specifically bind to a hydrophobic cell wall protein of the *Candida* genus wherein said protein has a molecular weight of about 38kDa and pharmaceutical compositions comprising said antibodies. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature for each of Groups I-VI is the specific binding properties of the antibodies.

The special technical feature of each of Groups VII-XVI is the specific antibody used.

The special technical feature of each of Groups XVII- XXIII is the specific hydrophobic cell wall protein.

The special technical feature of Group XXIV is the methods steps utilized.

Claims 37 and 70 are linking claim, linking the invention of claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the

limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
December 6, 2004